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Minnesota Board of Pharmacy

University Park Plaza
2829 University Ave SE, Suite 530
Minneapolis, MN 55414-3251
www.phcybrd.state.mn.us

Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions during the time period of September 1, 2004, through November 30, 2004.

Pharmacists

Evenson, Jon A., License No. 115013-7. Licensee admitted to the theft of controlled substance drugs from his employer and the unauthorized personal use of controlled substance drugs. Licensee was placed on probation with the Minnesota Board for three years, subject to certain conditions, or until he successfully completes a participation agreement through the Health Professional Services Program (HPSP), whichever is longer.

Gorecki, Craig J., License No. 114400-4. Licensee was found to have violated a previous Stipulation and Order of the Board based on his noncompliance with his participation agreement with the HPSP by subverting the monitoring of his hydrocodone use by providing false information to HPSP. Licensee was suspended for an indefinite period of time, but the suspension was stayed and the licensee was placed on probation with the Board for a minimum of five years, subject to specified conditions.

Pharmacy Technicians

The following pharmacy technicians had their registration revoked.

Carroll, Sandra J., Registration Number 707911-5. Registration was revoked after the registrant was caught stealing controlled substance drugs from her place of employment resulting in a criminal complaint being filed against her.

Jachymowski, LeAnn M., Registration Number 705550-8. Registration was revoked after the registrant was found to be filling prescriptions for herself without authorization from a licensed practitioner.

Mueller, Dawn Marie, Registration Number 701062-4. Registration was revoked when this individual was found to be refilling her own prescriptions without authorization from a prescriber.

Yurick, Rebecca A., Registration Number 706572-1. Registration was revoked when this individual was caught stealing controlled substance drugs from her employer.

Continuing Education Records

The Board is in the final stages of completing the audit of continuing education (CE) participation for the two-year period, October 1, 2002, through September 30, 2004. At the conclusion of each CE reporting cycle, the Board audits 10% of Minnesota-licensed pharmacists and requires that copies of the certificates of participation or other documents be submitted to the Board.

Minnesota pharmacists who have not received an audit notice from the Board can now safely dispose of CE records from the 2002 to 2004 reporting period. Those pharmacists who did receive notification that they have been selected for audit are expected to submit the evidence of CE participation to the Board prior to the end of December. Individuals selected for audit can destroy their CE participation records after they have received acknowledgement from the Board that the documents they submitted have met the Board's audit requirements.

Board Votes to Discontinue Practical Examination

At its meeting of October 20, 2004, the Board of Pharmacy concluded a lengthy debate on whether or not it should continue to require a written practical examination as part of the Board's requirement for original licensure. The Board voted to discontinue the practical examination after the January 2005 administration.

During its deliberations on whether or not to continue the practical examination, the Board obtained information from other states that require practical examinations and from the National Association of Boards of Pharmacy® (NABP®). NABP has completed its development of an updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®), which goes into effect in May 2005. The Board found that the competency areas being tested for in its practical examination would now be covered in the updated NAPLEX. As a result, the Board felt that it could discontinue its written practical examination and rely solely on the NAPLEX and Multistate Pharmacy Jurisprudence Examination® in determining entry-level competence for pharmacist licensure.

Candidates for original licensure in Minnesota, who will be taking the examination in January 2005, will be the last group that is required to take the Board's written practical examination. The end of an era is truly at hand.

The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- Persons aged 65 years or older;
- Children six to 23 months of age;
- Residents of long-term care facilities and nursing homes;
- Persons two to 64 years of age with chronic medical conditions;
- Health care workers involved in direct patient care;
- Household contacts and out-of-home caregivers of children less than six months of age;
- Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- Washing your hands frequently to avoid the spread of viruses and bacteria;
- Avoiding contact with people who may be sick;
- Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- Covering your mouth and nose when coughing or sneezing;
- Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at www.hhs.gov/nvpo/pandemicplan. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – www.fda.gov/oc/opacom/hottopics/flu.html.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – www.cdc.gov/flu.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com as well as FDA's distributed a press release that is now available at www.fda.gov.

Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.

Diabetes or Alzheimer's Disease?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Several reports of mix-ups have been reported in which the antidiabetic agent **AMARYL®** (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication **REMINYL®** (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's *2005 Survey of Pharmacy Law* CD-ROM is now available. Eight new questions were added to this year's *Survey;* topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. If you do not have Web access or would like more information on the *Survey,* please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net, or contact NABP at 847/391-4406 or custserv@nabp.net.

Adverse Event Reporting

During the last legislative session the Health Related Licensing Boards, including the Board of Pharmacy, were added to a piece of legislation that requires the reporting of adverse medical events. The Board is now required to report to the Minnesota Department of Health all instances of adverse medical events (such as dispensing errors) that come to its attention.

While the legislation did not require the reporting of dispensing errors by pharmacists to the Board, consumers bring approximately 60 to 80 dispensing error complaints to the Board's attention each year. It has been the Board's experience that how dispensing errors are handled at the pharmacy level largely determines whether or not a complaint is filed with the Board regarding the error.

Most prescription errors are resolved between the pharmacist and the patient. Pharmacists should be sure to document the error internally as part of the pharmacy's ongoing quality assurance program that addresses medication errors and ways to prevent similar occurrences.

All errors, and even near misses, should be periodically reviewed internally so that flaws in the medication delivery system can be corrected and the occurrence of similar errors prevented. Most patient complaints to the Board are accompanied by reports of less-than-adequate remediation by the pharmacy and/or pharmacist in response to the complaint or concern.

When dealing with patients, in response to a question or comment regarding a possible medication error, the Board's Committee on Professional Standards recommends that the following be considered:

1. Have the pharmacist on duty handle the issue rather than technical or support staff.
2. Assume that the patient is correct and that an error has occurred until an investigation provides proof to the contrary.
3. Take the error/complaint seriously and do not trivialize it to the patient with statements such as "Mistakes will happen," "Well, at least you didn't take any," or "Just bring it back to the pharmacy and we will give you a refund."
4. Show genuine concern for the health and well-being of the patient, especially if he or she has consumed some of the erroneous medication. Contact the prescriber and follow-up with the patient by phone or return visit to see how the patient is doing.
5. Sincerely apologize and let the patient know that the error/complaint will be communicated to the management/owner and that steps will be put in place to prevent a similar incident in the future.

Although you may feel that some complaints or questions about dispensing issues are without merit, it is advisable to truly listen to the consumer and resolve any complaints before they reach the Board.

Crackdown on Methamphetamine – A Legislative Priority

Preliminary indications are that a crackdown on methamphetamine use and abuse in Minnesota is going to be a legislative priority in the 2005 Legislative Session. Among the areas where the Board has been contacted for input is the restriction of sales and distribution of methamphetamine precursors such as ephedrine and pseudoephedrine and products containing those items.

Pharmacists are encouraged to voluntarily participate in the "Meth Watch" program being supported by the Minnesota Pharmacists Association. Pharmacists can play an important role in preventing the large-scale diversion of pseudoephedrine to clandestine methamphetamine labs in Minnesota. All pharmacists are encouraged to monitor pseudoephedrine sales and to keep pseudoephedrine-containing products in an area where the theft or diversion of those products is eliminated.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

David E. Holmstrom, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Reneeta C. "Rene" Renganathan - Editorial Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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